PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Toshiki NANKO et al.

Group Art Unit: 1724

Continuation-in-part of Application
Serial Number: 08/930,271

Examiner: I. Cintins

Filed: July 22, 2003

For: DEVICE FOR BODY FLUID PURIFICATION AND SYSTEM FOR BODY FLUID PURIFICATION

PRELIMINARY PAPER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

July 22, 2003

Sir:

The present continuation-in-part application has been filed to provide a description of the unexpected properties shown in the declarations under 37 C.F.R. § 1.132 filed in the parent application, Serial No. 08/930,271. During an interview on March 12, 2003, with Mr. Ivars Cintins, the Examiner in charge of the parent application, Mr. Cintins indicated that although the claimed range of particle size of 460 to 600 μm (recited in claim 11 of the parent application as amended in the amendment filed January 27, 2003) appears to be properly supported (under 35 U.S.C. § 112) in

the application, he could not properly consider the unexpected properties demonstrated by the data of the declarations of Akira Kobayashi for this range of particle size, because the properties are not disclosed in the application. Mr. Cintins noted that the decision of the Court of Custom and Patent Appeals in the case of *In re Davies*, 177 USPQ 381 (1973) supports a position that the Office need not consider evidence relating to "after-discovered" properties.

A description of the unexpected properties demonstrated in the Kobayashi declarations has been inserted in the present (continuation-in-part) application on page 29, lines 2-8. Specifically, the following description of unexpected properties, which is not included in the parent application, has been added to the present application:

> "Spherical hydrogel particles comprising a cellulose and having an average particle size of 430 to 600 μm and, more particularly, 430 to 500 μm, provide a significantly higher passing ratio for leukocytes and erythrocytes as well as platelets passing through a column packed with the particles and produce an insignificant change in pressure difference during the passing of blood through the column as compared to smaller particles."

This description does not affect the applicants' rights to the

benefit of the filing date of the prior application under 35 U.S.C. § 120 for the claims in this application, which correspond substantially to the claims remaining in the parent application (claims 11, 14, 18, 19, 21-24, 28 and 29) as of the filing date of the present application. As noted by the court in *Davies*:

> "[W]e see no impediment to the present appellants' refiling their application and incorporating a discussion of the allegedly unobvious properties while retaining the effective date of the application involved here through § 120."

The description of unexpected properties added to this application is sufficient to support consideration of the unobvious properties shown by the data of the Kobayashi declarations and, consequently, an allowance of the claims of the present application.

The present application describes (page 29, lines 2-8) that spherical hydrogel particles comprising a cellulose and having an average particle size of 430 to 600 μm and, more particularly, 430 to 500 μm, provide a significantly higher passing ratio for leukocytes and erythrocytes as well as platelets passing through a column packed with the particles and produce an insignificant

change in pressure difference during the passing of blood through the column as compared to smaller particles. This description is consistent with the data of the Kobayashi declarations, which demonstrate that there is a significantly higher passing ratio of platelets through columns packed with hydrogel particles having particle sizes of 430 μm and 500 μm as compared to the passing of platelets through columns packed with smaller hydrogel particles, such as 300 μm and 400 μm. As noted by the Examiner in the outstanding Action dated April 22, 2003, in the parent application, the "unexpected property associated with hydrogel particles having the recited particle size has not been disclosed in the application originally filed". (Page 6, lines 4-6). (Emphasis added).

It is noted that although the hydrogel particles used in the experiments described in the Kobayashi declarations are epoxidated cellulose particles having hexadecylamine immobilized thereon in an amount 100 to 300 μmol per gram of dry weight of the epoxidated cellulose and the weight ratio of the epoxidated cellulose to water in the adsorbent is 2:8, it is unnecessary to limit the description of unexpected properties in the present application to these more limited particles because the unexpected properties are not limited

to the use of these particles. The use of more limited particles in the experiments in the declaration is relevant, at best, only to the scope of the claims supported by the showings.

The description and data of the Kobayashi declarations demonstrate the non-obviousness of the device and system recited in the claims of the present application for the reasons explained in the response filed January 27, 2003, in the parent application to the Action dated July 25, 2002, and the response filed June 26, 2002, to the Action dated February 26, 2002.

As noted in these responses, the data of the Kobayashi declarations, demonstrate that there is a significantly higher passing ratio of platelets through columns packed with hydrogel particles having particle sizes of 430 μm and 500 μm as compared to the passing of platelets through columns packed with smaller hydrogel particles, such as 300 μm and 400 μm. These data establish unexpected results for particles having an average particle size within the range of 430 to 500 μm and support the patentability of the claimed range of 460 to 600 μm.

First, regarding the lower limit of particle size of 460 μm recited in the claims, it is not necessary to recite a particle

size of 430 μm, because if the properties obtained for hydrogel particles having an average particle size within the range of 430 μm to 500 μm are unexpected (as demonstrated by the data of the declarations), the properties for hydrogel particles having an average particle size of 460 μm are *prima facie* unexpected.

Second, regarding the upper limit of particle size of 600 μm recited in the claims, as explained in the response filed June 26, 2002, a material increase (or decrease) in the passing ratio of the platelets when the average particle size of the adsorbent is between about 500 and 600 μm is not likely to occur. The clearance between the adsorbent particles through which blood cells pass increases as the average particle size increases. It is presumed that the passing ratio of blood cells is greatly influenced by the contacting of the blood cells with the adsorbent particles in the device for blood fluid purification, but the frequency that the blood cells contact the adsorbent particles decreases as the particle size of the adsorbent increases and as the clearance between the adsorbent particles through which blood cells pass also increases. Therefore, the probability of a material change when the average particle size of the adsorbent is between about 500 and

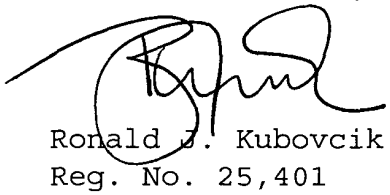
600 μm is low. Additionally, a showing of criticalness for the upper limit of 600 μm, *per se*, is not required because the prior art does not support the obviousness, when the data of the Kobayashi declaration are considered, of the use of spherical hydrogel particles having an average particle size outside the range of 460 to 600 μm.

Favorable consideration of the patentability of the claims of the present application is believed to be in order and is respectfully requested.

In the event any fees are required in connection with this paper, please charge our Deposit Account No. 111833.

Respectfully submitted,

KUBOVCIK & KUBOVCIK



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